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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/654,368

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Jon P. St. Germain

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EXAMINER

LEE, YUN HAENG NMN

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/654,368	Applicant(s) ST. GERMAIN ET AL.	
	Examiner Yun H. Lee	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,22,29,40,49 and 74-111 is/are pending in the application.
- 4a) Of the above claim(s) 3,11,14,22,40,82,85,93,96,101,102,109 and 110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,12,13,15,16,29,49,74-81,83,84,86-92,94,95,97-100,103-108 and 111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election in the reply filed on 7/5/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicant's election of species in the reply filed on 7/5/2006 was incomplete. In a telephone conversation with Diane Wong on 8/16/2006, Examiner clarified the election of species requirement. Applicant further elected the subspecies wherein the balloon is expanded by filling with carbon dioxide; the subspecies wherein the expandable member is expanded to fully obstruct the aorta; and the subspecies wherein the physiological parameter measured is blood pressure.
3. Claims 1, 2, 4-10, 12, 13, 15, 16, 29, 49, 74-81, 83, 84, 86-92, 94, 95, 97-100, 103-108 and 111 are being considered for examination in accordance to Applicant's election. Claims 3, 11, 14, 22, 40, 82, 85, 93, 96, 101, 102, 109 and 110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and/or inventions, there being no allowable generic or linking claim.

Claim Objections

4. Claims 75 and 89 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s)

in proper dependent form, or rewrite the claim(s) in independent form. Currently, these claims have identical limitations to their parent claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-8, 10, 13 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goetz et al. (US Pat. No. 3,692,018).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 9 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goetz et al. (US Pat. No. 3,692,018). Goetz et al. discloses that air flows into the inflatable member and expandable member, or balloon (col. 3 lines 14-15). Air inherently contains carbon dioxide. In the alternative, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use carbon dioxide to fill the inflatable member and

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expandable member, or balloon, because Applicant has not disclosed that using carbon dioxide provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the invention of Goetz et al. Therefore, it would have been an obvious matter of design choice to use carbon dioxide to fill the inflatable member and expandable member, or balloon, of Goetz et al.

9. Claims 2, 29, 49, 74-81, 84, 86-92, 94, 95, 98, 103-106 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US Pat. No. 3,692,018).

Regarding claim 2, it would have been obvious to one of ordinary skill in the art to configure any of the expandable members, inflatable members, or balloons to have a volume between 10-30 cc since the volume just needs to be enough to sufficiently obstruct the aorta to achieve the purposes of cardiac assistance. The exact volume would be case-specific and dependent on the particular subject aorta size. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 29, 74 and 75, Goetz et al. discloses that there can be one or more inflatable pumping chambers (col. 2 line 32). Thus, it would have been obvious to have three or four balloons. At any rate, any additional balloons are just a duplication of the

inflatable member. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 49, it would have been an obvious matter of design choice to insert the catheter into a subclavian artery because Applicant has not disclosed that inserting the catheter into a subclavian artery provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the method of Goetz et al. wherein the catheter is inserted in a femoral artery because both methods facilitate accessing the aorta. Therefore, it would have been an obvious matter of design choice to insert the device of Goetz et al. into a subclavian artery to obtain the invention as specified in claim 49. In this case, it would further be obvious to place the inflatable member proximal (relative to the catheter) to the expandable member since the approach would be vertically opposite.

Regarding claims 76, 77, 91, 94, 103 and 111, see the above discussion of claims 9 and 12.

Regarding claims 78 and 84, see the above discussion of claim 2.

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Regarding claims 79-81, 86-90, 92, 95, 98 and 104-106, the limitations are clearly met by Goetz et al.

10. Claims 15, 83, 97, 99, 100, 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US Pat. No. 3,692,018) in view of Karcher et al. (US Pat. No. 4,697,574).

Regarding claims 15, 83 and 97, Goetz et al. discloses measuring an electrocardiogram (col. 3 line 55) and inflating when the heart is relaxed, or diastole, and deflating when the heart is pumping, or systole (col. 3 lines 45-50). Karcher et al. further teaches, in detail, measuring an electrocardiogram and synchronizing inflation with the R wave of the electrocardiogram, so that maximum inflation occurs at the peak of the T wave, and deflation is timed to occur just before the next QRS complex of the electrocardiogram (fig. 1, col. 2 line 63 – col. 3 line 2). Karcher et al. teaches that this is done so as not to interfere with the blood circulation in the aorta and also that this synchronization is very important for the hemodynamic efficiency of the system of circulatory assistance (col. 3 lines 3-9). Thus, it would have been obvious to one of ordinary skill in the art to configure the invention of Goetz et al. to synchronize inflation with the R wave of the electrocardiogram, so that maximum inflation occurs at the peak of the T wave, and deflation is timed to occur just before the next QRS complex of the electrocardiogram.

Regarding claims 99, 100, 107 and 108, Karcher et al. teaches of measuring blood pressure (13) upstream the expandable member and adjusting the expansion of the

expandable member based on the measurement (col. 3 lines 10-12). Karcher et al. further teaches that the synchronization is insured both on the signals from an ECG and on the pressure signals because of the importances mentioned above in the discussion of claims 15, 83 and 97. Thus, it would have been obvious to one of ordinary skill in the art to configure the invention of Goetz et al. to measure blood pressure upstream the expandable member and adjust the expansion of the expandable member based on the measurement.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766

yhl